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OTITIS MEDIA WITH EFFUSION: ITS SIGNIFICANCE : IN THE DEAF STUDENT

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WILLIAM A. POLLAN, D.O.

THESIS

Presented to the Faculty of The University of Texas

Health Science Center at Houston

School of Public Health

in Partial Fulfillment

of the Requirements

for the Degree of

MASTER OF PUBLIC HEALTH

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON SCHOOL OF PUBLIC HEALTH

June 1982

ACKNOWLEDGEMENTS

I am grateful,

To the staff of Sunshine Cottage School for the Deaf in San Antonio, Texas and to my wife Sherry, a deaf educator of that school, for their help and cooperation in acquiring the data to write this paper. Without their dedication to their profession and their students, the impetus to write this paper would never have emerged.

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INTRODUCTION

Otitis media with effusion currently ranks as the most common cause of hearing loss in children of preschool and school age. In the literature effusion rates as high as 68% are reported. Teele 42, in a recent study released in 1980, reported that an estimated 30% of all children have had three or more occurrences of effusion by the age of two. Studies 10,23,33,37,41 done in schools for the deaf indicate that the incidence of otitis media with effusion in the hearing impaired population is greater than the incidence in the normal population. An estimated 25 to 30 percent of hearing impaired children, at any one tympanometric screening, will have tympanograms consistent with middle ear effusion.

Herein lies the problem. Otitis media with effusion imposes a conductive hearing loss on an already existent sensorineural hearing loss. Most children with sensorineural hearing losses are dependent on sound amplification equipment (hearing aids) for communication. The loss of as little as 5 to 10 decibels in their hearing threshold due to a conductive loss may make the difference between meaningful utilization of residual hearing for communication and not hearing at all. This conductive loss makes the difference between usable auditory input and useless noise. 41

The etiology of otitis media with effusion is uncertain. Its educational, emotional, and medical consequences, however, are not. Present day medical treatment is questionable and prevention is diffiuclt, if not impossible.

The presence of the disease and its resultant decrease in conductive hearing, however, are indisputable facts.

This paper will explore the extent of otitis media with effusion, its effects, what methods are available for detection, current and future methods of medical management, make recommendations for a screening program for otitis media in schools for the deaf, and propose a study to establish the incidence of otitis media with effusion in the deaf population. To this author's knowledge, no such review of otitis media with effusion and its effects on the hearing imapired community has been published.

OTITIS MEDIA WITH EFFUSION: WHAT IS IT AND HOW WIDESPREAD

"Otitis media with effusion" (OME) is the official title adopted by the ad hoc committee on the Classification of Otitis Media that met in Columbus, Ohio in 1980. OME encompasses all maladies previously known as: serous otitis, glue ear, secretory otitis, non-suppurative otitis, chronic otitis media, mucoid ear, allergic otitis and numerous others. Simply defined OME is any disease entity or condition which results in a painless accumulation of serous or mucoid fluid in the middle ear space. There are presently two widely accepted theories of this pathogenesis: the "ex vacuo theory" and the "inflammatory thoery".

The "ex vacuo theory" was first proposed by Politzer³² in 1867. The hypothesis is that eustachian tube dysfunction causes a chronic negative pressure in the middle ear which results in a transudate in the middle ear space. Proponents of this theory postulate two types of eustachian tube dysfunction: mechanical and functional. Mechanical obstruction is thought to be due to edema of the eustachian tube mucosa. It also occurs secondary to a mass blocking the eustachian tube – an uncommom occurrence. Functional obstruction occurs when tubal stiffness or rigidity is decreased as seen in poorly developed eustachian tube cartilage. Another important factor concerning eustachian tube dysfunction is an inefficient active opening mechanism. Bylander² showed that eustachian tube muscular opening function is significantly poorer in children than adults, and significantly poorer in younger children than older children. The ultimate result of any type of obstruction of the eustachian tube is non-ventilation of

the middle ear space. This lack of ventilation results in a negative middle ear pressure followed by a transudate (effusion) into the middle ear space.

The "inflammatory theory" proposed by Brieger ¹⁴ in: 1914 hypothesizes that the fluid in the middle ear is secondary to an inflammatory reaction and, therefore, is an exudate rather than a transudate. This theory has its proponents supported by studies such as Sades. ³⁸ He reported that his studies showed the basic histopathological mechanism in OME is an inflammatory hypertrophy of the middle ear mucous membrane and hyperplasia of its mucous glands.

These two theories function as the cornerstones of current medical management of OME. But before becoming concerned with how to treat OME, has it been determined that OME is widespread enough to warrant treatment?

OME currently ranks as the most common cause of hearing loss in the preschool and school age population. Bluestone and Shurin showed that effusions may occur in as many as 68% of children in the first two years of life. A longitudinal study by Eagles in the 1960's involved 1,191 public school children. He found during the study period of five years that 29.6% of the children had or developed otoscopic abnormalities consistent with OME. It is now estimated that 20% of the children in the United States are suffering from fluctuating hearing loss secondary to OME.

As great as the incidence of OME is among non-handicapped children, it is even greater among hearing impaired children. Mehta and Erlich ²⁸ found a 34% overall incidence of OME in a three year study at a school for the deaf. Rubin ³⁷ found an incidence of 30% in a 3-6 year old hearing impaired population. Stool ⁴¹ reported an overall incidence of 29% for his 2-21 year old hearing impaired study group. His findings of a 64% incidence in the 2-5 year old age group in the same study seems somewhat elevated. All these studies reveal an

apparent inverse relationship between incidence of OME and age. The incidence of OME is at its peak in the 2-8 year old age group. In the older age groups the incidence of OME decreases so as to be virtually non-existant by 14 years of age.

Another factor which seems to affect the incidence of OME is the season of the year. Stool 41 reported shifts in incidence depended on the season of the year during which the screening was accomplished. There appeared a six fold increase in OME in the preschool children from fall to spring. Yet over the same time period, the incidence rate for high school students remained constant – again showing the age/incidence relationship.

Two key factors seem to affect the distribution and incidence of OME. OME increases with certain seasons - the greatest increase seen in winter and spring. It also increases inversely with age - the 3-5 year old preschool population having the greatest incidence. Other less important factors also contribute. Epidemiologic studies indicate that OME is more prevalent among males, American Indians, and Eskimos. ⁴² It has been suggested that environmental factors such as living conditions, socioeconomic status, and air pollution are all contributors. ¹² Jaffe ¹⁸ reports that children with congenital sensorineural hearing loss may have certain bony skull anomalies which affect the eustachian tube leading to a higher rate of eustachian tube dysfunction. All these elements suggest a multifaceted disease entity with multietiological factors influencing its rate of occurrence and distribution in the population.

EFFECTS OF MIDDLE EAR EFFUSION

Otitis media with effusion appears to be associated with numerous pathological conditions. Smyth 40 feels that a chronic state of OME causes a change in the fibrous tissue layer of the tympanic membrane. This results in membrane hyalinization, permanent perforation, or development of retraction pockets and cholesteatoma. All of these conditions lead to ossicular chain damage. Tympanic membrane atrophy, atelectasis, and tympanosclerosis have all been documented in patients with prolonged middle ear negative pressure secondary to OME. As noted by Healy 14 "almost all pathologic conditions affecting the tympanic membrane, middle ear, and mastoid complex, with the exception of otosclerosis, probably have their origin in otitis media with effusion".

In the past, much of the focus of concern regarding OME centered on the medical pathologic conditions which resulted after a chronic state developed. All medical treatment focused on preventing these pathologic conditions. Very little emphasis was placed on the educational impairments caused by the disease and its sequelae. It was generally felt that the conductive hearing loss associated with OME was merely a mechanical blockage. The sound reaching the middle ear was decreased but no long lasting effect on speech, language, or intellectual development was seriously contemplated.

The variable hearing loss associated with OME during the intellectual formative years, from infancy to ten years of age, appears to have an unfavorable effect on educational development. Ling²⁶ reviewed the available

literature in 1972 and concluded that "there is some evidence to support the view that serious retardation may be caused by hearing impairments secondary to chronic otitis media". Downs and Webster, while giving a 'short course' at the 1978 American Speech and Hearing Association convention in San Francisco, California, stated that hearing thresholds reduced by even 15 decibels can be detrimental to children learning a language. Katz²¹ and Rapin³⁴ both reported educational and linguistic problems associated with the existence of OME in early childhood. These problems include delays in math and reading ability²⁵, significantly reduced verbal skills¹⁹, learning disabilities in the auditory mode²⁰, auditory processing deficits and disturbance in auditory-visual integration and auditory sequential memory, delays in word and sentence usage⁴⁴, and development of inefficient listening strategies.²⁴

In 1969 Holm and Kunze¹⁵ compared groups of children ages 5 though 9 years. One group had a fluctuating mild conductive hearing loss due to recurrent otitis media. The other group had no conductive hearing loss and no history of otitis media. They reported "the group who suffered from fluctuating hearing loss resulting from chronic otitis media were delayed in the acquisition of all language skills tested when compared with the matched control group".

Ventry⁴³ points out that there is a lack of controlled, carefully constructed, and properly designed studies of the effects of chronic otitis media on the speech and language development of children in the early years of life. The need for a well designed long term study in this area is evident. Enough data is available now, however, which would indicate that we should adopt the philosophy voiced by Lewis²⁴ in 1976. "Middle ear disease in young children should not be regarded as a benign condition that occasions few problems

other than physical discomfort and malaise. Educationally it is a potentially dangerous disability deserving urgent and aggressive interventions".

METHODS OF ASSESSMENT

At the present time there are six methods of detecting the presence of effusion in the middle ear: history, audiometry, brainstem evoked response audiometry, tympanocentesis/myringotomy, otoscopy, and impedance audiometry (tympanometry and assessment of the middle ear muscle reflex).

History: This method is often considered quite unreliable. A positive otologic history by the child, the parent, or the teacher may aid in discovering the effusion. A negative history does not, however, rule out the presence of OME since its symptamatology is often silent. It has been noted that in schools for the hearing impaired it is often the teacher who first notices a decrease in hearing acuity. The small student to teacher ratio allows a close association with the student. This association combined with constant monitoring of the child's responses to stimuli provides a base line of auditory functioning. From this base line the teacher is able to detect an early deviation. It is from this auditory awareness that numerous previously undetected cases of OME are discovered.

Audiometry: This method continues to play a key role in detection of OME in the non-hearing impaired population. The inability of this method to differentiate conductive from sensorineural hearing loss make it a poor method of identifying OME in the hearing impaired population. Since sensorineural hearing loss is often a dynamic ongoing process, mere detection of further hearing loss without differentiation as to type is of limited value.

Brainstem evoked response autiometry (SBER): Recently the use of this method has been proposed to make the differentiation as to type of loss. It appears there is an increase in the latency of one of the evoked brain waves in patients with middle ear effusions. ²⁹ Although BSER audiometry is an available supplement to audiological assessment, the fact that it should be performed by medical personnel limits its usefulness as a screening method. ²⁷

Tympanocentesis/myringotomy: This, of course, is the most reliable method of identifying OME. It is, however, invasive and frought with complications - anesthesia reaction, cholesteatoma, and tympanosclerosis, to name a few. This is the method most often used to validate the specificity of some other non-invasive methods.

Otoscopy (including otomicroscopy): This method remains the cornerstone of the diagnosis of OME by the medical profession. Effusion in the middle ear is most easily diagnosed when a fluid level or air bubbles are visible behind the tympanic membrane. Other less obvious but suggestive signs include a severly retracted tympanic membrane, reduced membrane mobility (evaluated by a pneumatic otoscope), and an increased thickness or dull appearance to the membrane. Otomicroscopy offers an even closer examination making the diagnosis verifiable. Trained otoscopists are, of course, the limiting factor in utilizing otoscopy as a screening method.

Impedance audiometry (tympanometry and assessment of the middle ear reflex): This method stimulates the most controversy in audiological circles. It was first used in 1965 as a clinical tool to evaluate middle ear function. Audiologists have lauded it as the "bright light" in the history of auditory screening. Unfortunately, the lack of validity studies among different populations using this technique is a major drawback. Validity is determined by

sensitivity - the ability to predict a diseased ear correctly and specificity - the ability to predict non-diseased ears correctly. Impedance screening has a high sensitivity but a low specificity. Certain authors feel that the low specificity rates could be greatly enhanced if all audiologists adhered strictly to the national impedance screening guidelines and utilized - 200 mmH_20 middle ear pressure as a referral criteria. 1,4,30,33

Measurement of the acoustic muscle reflex by itself appears to be too sensitive a screening method. Utilization in conjunction with impedance audiometry, however, greatly increases the specificity of both methods. 5

Otoscopy, impedance audiometry, and acoustic reflex utilized in combination as a screening technique offers both high sensitivity - 97% and high specificity - 90%. All six methods should be utilized whenever economic and feasibility factors allow. This would provide not only accurate diagnosis but also precise follow up in a screening program.

CURRENT THERAPEUTIC MANAGEMENT

Healy and Smith ¹⁴ reviewed the current treatment modalities for OME. The most common treatment regimens have evolved using the "ex vacuo theory" as a basis. An effort is made to decongest the mucous membranes lining the eustachian tube and middle ear. The mainstay medications used in this treatment philosophy are antihistamines, sympathomimetic amines, or a combination of the two. Although this regimen is the accepted standard of treatment, there is very little evidence or documented controlled studies to support its use. In fact, recent research shows the use of this regimen has little or no effect on the resolution of OME. ^{22,31} A notable exception is the use of antihistamines in allergy patients.

Recent research alludes to a 'possibly effective' medication to resolve middle ear effusion - corticosteroids. As usual, further research is needed before the validity of this practice can be established.

Gottschalk¹¹ reports that OME can be treated successfully by using a modified middle ear inflation technique as an adjunct to proper medical management. His data includes some 12,000 patients with claims of relief of symptoms and objective findings of serous otitis media in as high as 92% of the cases. He emphasizes the fact that he accomplished this rate without the use of intratympanic inflation tubes. He also believes that antihistamines and decongestants have no place in the treatment of OME. He reports they increase mucous viscosity and interfere with normal tubal function - often actually causing a

middle ear block. Unfortunately, it appears that his studies are uncontrolled and non-reproducible by other authors.

The "inflammatory theory" of OME has led to the use of antimicrobials. It has been theorized that long courses of high dose antimicrobials may normalize middle ear function. This theory is based on studies 13,38 which have isolated pathological organisms from middle ear effusion and have shown histological changes in middle ear and eustachian tube mucosa. Healy and Smith 14 performed a small pilot study involving two matched groups with OME of greater than twelve weeks duration. One group received antimicrobial therapy with a trimethoprimulated famethoxasole combination for four weeks. The other group received no treatment. Eighteen of the 25 patients treated with the antimicrobial regimen regained normal middle ear function. Only 6 of the 25 patients receiving no treatment regained normal function. This study strongly suggests that treating OME with antimicrobials for extended periods may have merit.

When pure medical treatment regimens fail, then surgical therapy is indicated. The use of intra-tympanic ventilating tubes has become a widely accepted therapeutic modality. It is rapidly becoming the most commonly performed surgical procedure in the United States. Approximately 80% of patients who receive ventilating tubes respond after one insertion and require no further treatment. This response rate is not gained without risk of complications. Complication rates as high as 11% have been reported in the literature. 23

Otorrhea, persistant perforation, cholesteatoma, and granuloma of the tympanic membrane are the complications most usually encountered.

Adenoidectomy advocates claim that adenoids produce a mechanical obstruction of the eustachian tube orifice. Another theory is that the adenoids harbor pathologic microorganisms which migrate up the eustachian tube because

it is in such close proximity. Again we find no controlled studies which either prove or disprove these theories. A recent study by Roydhouse 35 suggest that adenoidectomy is not beneficial. This is supported by Connelly 8 who presents evidence that adenoidectomy does not reduce the conductive hearing loss associated with OME and does not improve its rate of recurrence.

Holmquist's ¹⁶ studies have established a relationship between poor eustachian tube function and reduced size of the mastoid air cell system. It seems logical that by creating an air filled cavity in the mastoids of individuals with sclerotic mastoids that tubal function can be improved. ¹⁷ This simple mastoidectomy has been successful in severely resistant cases of OME.

Unfortunately, most of these procedures and treatments are utilized in combination with each other without controlled studies to evaluate their effectiveness. The need for controlled studies is obvious.

THE FUTURE OF OME THERAPEUTICS

Future therapeutics include possible use of the pneumococcal vaccine in children to deter the development of OME secondary to pneumococcal infection, development of greater penetrating anti-microbials specifically designed for use in the middle ear space, development of scilastic eustachian tube implants to normalize tubal function, and cochlear implants which partially correct hearing losses thus reducing the devastating effect of OME in the hearing impaired. The true hope for the future lies in determining the etiology of OME. Once the cause is clearly understood, then a cure is not far behind.

Large amounts of money and research are being utilized to discover this etiology which will solve the mystery of otitis media with effusion - the most common cause of hearing loss in children today.

CONCLUSIONS AND RECOMMENDATIONS

Otitis media with effusion is a multifaceted disorder of undetermined etiology. Evidence seems to point to a constellation of disease entities which produce OME. Its effects - pathological, educational, and emotional are numerous and varied. The fact that it is not a benign process, as most physicians once thought, is clearly evident.

Serous otitis media with effusion currently ranks as the most common cause of hearing loss in the preschool and school age population. A statistic worsened by the fact that the incidence of OME in severely to profoundly hearing impaired children is significantly greater than that found in the normal hearing population.

In both populations the group of 2 to 8 year olds has the highest incidence of OME. This incidence decreases as the populations age to become almost non-existent by age 14. The incidence rate also depends upon the time of year. Winter and Spring show the highest incidence of all the seasons. Environmental, socioeconomic, racial and sexual components also effect, though to a far less extent, the incidence of OME.

Healy¹³, in his microbiology studies, showed the physiologic sequelae of OME to be anything but benign. The actual educational, intellectual, and emotional detriments associated with OME are controversial to say the least.

Rapin²⁴, however, clearly showed a relationship between conductive hearing loss

secondary to OME and an unfavorable effect on scholastic performance and development of verbal skills. Lewis²⁴ seemed to best capture the importance of conductive hearing loss secondary to OME. He said "educationally it is a potentially dangerous disability deserving urgent and aggressive interventions".

The six methods currently used to detect effusion in the middle ear individually have poor diagnostic predictability. Used in concert, however, it is possible to detect OME not only at an early stage but with good validity. Bluestone and his ad hoc committee recommended using otoscopy and impedance audiometry (tympanometry and acoustic reflex) as the most valid screening program for OME. This combination offers an economical method, both temporal and monetary, of screening large numbers of students.

Once OME is discovered, it must be treated. The most frequently used non-surgical treatment regimen consists of antihistamines and/or decongestants. Kjellman 22 and 01son^{31} have both uncovered evidence that use of these drugs has no effect on the resolution of OME. Perhaps high dose antimicrobials for four to six weeks as suggested by Healy 13 or middle ear inflation techinques as suggested by Gottschalk 11 will be the non-surgical treatment regimens of the 1980's.

For treatment failures by non-surgical regimens, there remains the surgical placement of intratympannic ventilating tubes. Although complications do occur, it is generally believed that these complications are not sufficient to preclude the frequent use of this method.

The cornerstone of treatment is early detection by otological surveillance. With early detection medical and surgical intervention can be accomplished
to result in an attenuation of the conditions and optimal hearing restored.
The early restoration of optimal hearing in a normal hearing child is important
but is a necessity in the hearing impaired child.

Ruben and Fishman³⁶ recommend a complete otological evaluation (Table 1) every four months for hearing impaired children 5 years of age and younger. It appears that this frequency of evaluation would:identify almost all children who either have a middle ear effusion or a propensity for an effusion. They also recommend an evaluation every six months for hearing impaired children older than 5 years of age. The discrepancy between four month and six month intervals is due to a lesser incidence of OME in the older age group. These recommendations, although apparently medically and otologically sound, have yet to be proven in a controlled study. A proposed study by this author may be found in the final section of this paper.

The recommendations of this author are to routinely screen the entire hearing impaired student population twice a year (Fall and Spring). This screening should be done by the school audiologist using impedance audiometry (tympanometry and acoustic reflex). The otological referral should be based on the criteria recommended by the American Speech and Hearing Association (Table 2). This twice a year screening should not be the only screening done. A constant surveillance for any alteration in hearing threshold should be conducted by hearing impaired students'teachers. Whenever the teacher feels, objectively or subjectively, that the student might have a decrease in his or her conductive hearing, that student should be referred to the audiologist for evaluation. Should the student meet the ASHA criteria for referral, it should be done immedi-The otolaryngologist of referral needs to be familiar with the unique otological and educational problems of the hearing impaired. As eluded to earlier, referral for medical treatment does not necessarily alleviate the condition. The school audiologist should do weekly follow up evaluations of all children undergoing medical treatment for OME. If the condition has not

Table 1
Suggested Minimal Information to be Ascertained at Each Otological Examination

Hearing Aid

Presence

Function

Fit of Mold

Acceptance of Aid

External Auditory Canal

Cerumen

External Otitis

Middle Ear

Middle Ear Effusion

Tympanosclerosis

Tympanomastoiditis

Inner Ear

Change in Threshold

Vestibular Function

Otorhinolaryngological Examination Other Than Ear

Mouth

Teeth

Pharynx

Neck

Nose

Tongue

Salivary Orifices

Paranasal Sinuses

Palate

Tonsils

Larynx

Other

Language Development

Visual Acuity

Speech Development

Social Development

Voice

Neurological Development

Table 2
Middle Ear Screening Criteria Recommended by the American Speech and Hearing Association

Classification	Results of Initial Screening	Disposition
1. Pass	Middle ear pressure normal* or mildly positive/negative+ and AR present!	Cleared; no return
2. At risk	Middle ear pressure abnormald (and AR present) or AR absent (and middle ear pressure normal or mildly positive/negative)	Retest in 3-5 weeks a) if tymp. and AR fall into class 1. b) if tymp. or AR remain in class 2 fail and refer.
3. Fail	Middle ear pressure abnormal and AR absent	Refer

^{*} Normal - Pressure peak in range \pm 50 mm H_2O .

[!] Mildly positive negative - +50 to +100 mm $\rm H_20$ -50 to -200 mm $\rm H_20$

[!] Present - Pen or meter needle deflection judged to be coincident with the reflex eliciting stimulus at levels of 100 dB HL for contralateral stimulation, 105 dB SPL for ipsilateral stimulation at 1000 Hz.

[•] Abnormal peak outside the ranges described for classification 1.

AR - Acoustic reflex tymp. - tympanometry.

resolved in four weeks, the audiologist should contact the referral physician and arrange another otological evaluation. This continous monitoring and follow up should be sustained until the condition is resolved. The student's conductive hearing threshold should return to his/her established baseline before treatment is terminated.

Teacher surveillance and audiological screening are not sufficient to minimize the effect of OME in the hearing impaired. Parental and physician education is of utmost importance. The significance of even a minor conductive hearing loss in a hearing impaired child must be clearly understood by all individuals involved in his or her education and otological care. The educational, emotional, and pathological deficits that accompany OME in the hearing impaired are real and must be minimized.

The ability of a hearing impaired child to use his or her residual hearing to its maximum advantage is the cornerstone on which their education is built. The loss of as little as 10-15 decibels in their hearing may make the difference between usable auditory input and useless noise. Early detection and medical intervention are the only tools presently at our disposal to combat this loss. The return of the student's residual hearing to its normal level in as short a period of time as possible is the responsibility of all the teachers, audiologists, parents, and physicians associated with the student. It should never be forgotten that otitis media with effusion is the most common cause of hearing loss in children. This loss in the hearing impaired may make the difference between utilizing residual hearing for communication and not hearing at all.

STUDY PROPOSAL

Mehta and Erlich²⁸, Porter³³, Rubin³⁷, and Stool⁴¹ have all reported an increased incidence of otitis media with effusion (OME) in the hearing impaired population. They have arrived at this conclusion by comparing the rates of OME they have found in their deaf students with that of rates of OME in normal hearing students. The classic normal hearing OME rate studies used for comparison are those of Eagles⁹, Bluestone², and Teele⁴². The obvious shortcomings of using such comparisons include utilizing different otological screening methods, different criteria for ascertaining OME, and different frequency of evaluation periods.

Sunshine Cottage School for Deaf Children in San Antonio, Texas offers a unique opportunity to do a longitudinal cohort descriptive survey comparing hearing impaired and normal hearing students. At the Cottage a program has been initiated called "reverse mainstreaming". This program brings children of normal hearing into a deaf school to attend classes in a one to one ratio with hearing impaired students. This program offers the opportunity to study the incidence of otitis media with effusion in both the hearing and hearing impaired populations under the same environmental, educational, and evaluative conditions.

The primary objective of this study would be to determine whether hearing impaired children have a greater incidence of otitis media with effusion than their counterparts in the normal hearing population.

Definitions

Otitis media with effusion - a complex, diverse, disease entity of unknown etiology which results in the presence of effusion (an accumulation of fluid) in the middle ear space.

Normal hearing - consists of a range of hearing from no hearing loss up to a 27 decibel loss on pure tone audiometric testing.

Hearing impaired - a hearing loss of greater than 27 decibels in pure tone audiometric testing.

Impedance audiometry - impedance measurement is achieved through the use of an impedance audiometer which measures the compliance in mobility of the tympanic membrane while varying the air pressure in the external ear canal. It also measures the middle ear volume when the eardrum is at its most compliant position.

Methods

The study population will be composed of three groups. Group I will consist of eight three-year olds. One half will be hearing impaired and the other will have normal hearing. Group II will consist of eight four-year olds equally divided and Group III will consist of eight five-year olds also equally divided between hearing impaired and normal hearing. These three groups have been chosen for two reasons: (1) Stool⁴¹, Rubin³⁷, and Bluestone³ showed the greatest incidence of OME to be in the 3-5 year old age group. This age grouping gives the greatest return for numbers studied. (2) There is an existing program at Sunshine Cottage which divides the children into the three age groups.

All three groups will be examined by a board certified otolaryngologist prior to beginning the study and on an annual basis during the study. Ear canals

with excessive cerumen will be irrigated and cleaned. Based on criteria of tympanic membrane color, mobility, and texture an evaluation of middle ear status will be reached concerning presence or absence of middle:ear effusion.

Once it has been determined that there is no external ear blockage nor middle ear fluid otologically, then impedance audiometry base line studies shall be established. The impedance audiometry testing shall be performed every four months as recommended by Rubin and Fishman has been determined by Rubin and Fishman by the American Speech and Hearing Association (ASHA) certified audiologist at the school. ASHA impedance audiometry middle ear screening criteria (Table 2) will be used to determine the presence or absence of middle ear effusion. Impedance audiometry evaluation shall also be done whenever a student is referred to the audiologist by a parent or teacher who feels a student has a hearing decrement. Any student failing the ASHA criteria shall be referred to an otolaryngologist for otological evaluation and treatment.

The study length should be at least three years and preferably four to five years. Three years would provide 40 study subjects and four years would provide 48 study subjects. The minimum three year length allows the study to follow the original three-year old group through the years of their greatest susceptibility to OME. All testing results, age, sex, and hearing status shall be compiled by the in-residence audiologist. A supplementary log of treatment protocol and recovery time should be kept.

Expected Results

If previous studies are correct, then a significantly greater incidence of OME should be found in the hearing impaired population. Unfortunately the scarcity of students in the study population make it quite difficult to determine if any difference found is statistically significant. In order to

determine a "p" factor of .05 for statistical significance the minimum size of the study group should be 40 subjects. It is clear that a larger study group would lend itself to better statistical evaluation. This can be accomplished by either lengthening the time of the study in order to increase the numbers or by increasing the number of people in the study. In order to increase the number of people, Sunshine Cottage would have to increase the size of its "reverse mainstream" program or the study would have to be carried on in similar programs around the country.

So far no study has been carried out for a sufficient period of time nor has had enough subjects to indicate that there is a statistically significant difference in incidence of OME between the hearing impaired and the normal hearing. If this study could be carried out as planned it could solve that uncertainty.

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William A. Pollan, D.O. was born 19 May 1950 in Houston, Texas, the son of Ellen Hopkins Pollan and David D. Pollan, JD. After completing his studies in 1968 at Strake Jesuit College Preparatory, Houston, Texas, he entered Baylor University in Waco, Texas. He graduated with a Bachelor of Arts and a major in psychology in December 1972. He then was employed as supervisor of employment at Dresser Industries Petroleum and Minerals Group in Houston, Texas until August 1974 when he entered medical school at Kansas City College of Osteopathic Medicine. Dr. Pollan graduated in May 1978 receiving a degree of Doctor of Osteopathic Medicine. He immediately entered active duty with the United States Air Force and was commissioned as a Captain in the Medical Corps and assigned to Malcolm Grow Medical Center, Andrews AFB, Washington, D.C. for his internship. Upon completion of internship in July 1979 he was assigned to Bergstrom AFB, Texas. Dr. Pollan served as a squardon flight surgeon, chief of environmental medicine, and chief of flight medicine until September 1981 when he entered an Aerospace Medicine Residency.

During his tour at Bergstrom AFB, Texas he received the Meritorious Service Medal, three Tactical Air Command Certificates of Appreciation, and was selected as the 1980 Tactical Air Command Flight Surgeon of the year.

Dr. Pollan is a Diplomate of the National Board of Examiners for Osteopathic Physicians and Surgeons and holds a Texas State License to practice medicine.

He was married to Sherry Taylor in June 1973 and they have one child, a daughter, Rebecca Ann born 13 September 1979.

Permanent address:

3418 River Way San Antonio, Texas 78230

This thesis was typed by Janie Brooks

